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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1315]

Draft Guidance for Industry on How to Use E–Mail to Submit Information to the Center for Veterinary Medicine; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance for industry (#108) entitled ''How to Use E–Mail to Submit Information to the Center for Veterinary Medicine.'' This draft guidance is neither final nor is it in effect at this time. The draft guidance document is intended to provide guidance on how to submit information to the Center for Veterinary Medicine (CVM) as an e-mail attachment by Internet. These electronic submissions are part of CVM's ongoing initiative to provide a method for paperless submissions. This draft guidance implements provisions of the Government Paperwork Elimination Act (GPEA).

DATES: Submit written comments on the draft guidance at any time, however, comments should be submitted by [*insert date 60 days after date of publication in the* **Federal Register**], to ensure their adequate consideration in preparation of the final document. Submit written comments on the information collection requirements by [*insert date 60 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the full title of the draft guidance document and the docket number found in brackets in the heading of this document.

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Copies of the draft guidance document entitled ''How to Use E–Mail to Submit Information to the Center for Veterinary Medicine'' may be obtained on the Internet from the CVM home page at http://www.fda.gov/cvm/. Persons without Internet access may submit written requests for single copies of the draft guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the collection of information requirements to the Dockets Management Branch (address above). Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578, e-mail: jmessenh@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 20, 1997 (62 FR 13430), FDA published the electronic records and electronic signatures final regulation. This regulation (part 11 (21 CFR part 11)) provides for the voluntary submission of parts or all of regulatory records in electronic format without an accompanying paper copy. This rule also established public docket number 92S–0251 to provide a permanent location for a list of the documents or parts of documents that are acceptable for submission in electronic form without paper records and the agency units to which such submissions may be made. CVM will identify in this public docket the types of documents which may be submitted in electronic form as those documents are identified in final guidance or regulations. This docket is accessible on the Internet at http://www.fda.gov/ohrms/dockets/dockets/92s0251/92s0251.htm. The GPEA of 1998 (Public Law 105–277) requires Federal agencies, by October 21, 2003, to provide: (1) For the option of the electronic maintenance, submission, or

disclosure of information, if practicable, as a substitute for paper; and (2) for the use and acceptance of electronic signatures, when practicable.

CVM accepts certain types of submissions by e-mail with no requirement for a paper copy. These types of documents are listed in public docket number 92S–0251 as required by § 11.2. CVM's ability to receive and process information submitted electronically is limited by its current information technology capabilities and the requirements of the electronic records and electronic signatures regulation. This guidance outlines general standards which should be used for the submission of any information by e-mail.

II. Significance of Guidance

This Level 1 draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represent's the agency's current thinking about using e-mail to submit information electronically. It does not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulation, or both.

III. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: How to Use E–Mail to Submit Information to the Center for Veterinary Medicine.

Description: CVM is responsible for developing and administering guidances that explain how to adhere to the electronic records and electronic signatures regulations (part 11). The electronic records and electronic signatures regulations provide for the voluntary submission of parts or all of regulatory records in electronic format without an accompanying paper copy. These regulations comply with the GPEA. The GPEA requires Federal agencies, by October 21, 2003, to give persons who are required to maintain, submit, or disclose information the option of doing so electronically when practicable as a substitute for paper.

The draft guidance document describes the procedures for persons who are sponsors of new animal drugs who wish to file submissions by e-mail. The draft guidance instructs those who wish to submit information to CVM by e-mail to first register with them. Registration entails sending a letter to CVM with a sponsor password and the names, phone numbers, and mail and e-mail addresses of a sponsor coordinator and any person who will submit information electronically to CVM. This letter is sent on paper and electronically. Other information collection provisions described in the guidance are the submission of e-mails with the individual passwords of those who submit information electronically and e-mails with any changes to the sponsor's registration. CVM will use all the information submitted to process electronic submissions.

Description of Respondents: The likely respondents to this collection of information are new animal drug sponsors.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
190	0.74	140	1	140

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimates in table 1 of this document resulted from discussions with new animal drug sponsors.

IV. Comments

The draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document. Submit written comments by [*insert date 60 days after date of publication in the* **Federal Register**], to ensure adequate consideration in preparation of the final document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document.

Submit written comments concerning the information collection requirements to the Dockets Management Branch by [*insert date 60 days after date of publication in the* **Federal Register**].

A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 3-16-00

Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 00–???? Filed ??–??–00; 8:45 am]

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